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Environmental
Protection Agency

DPR Regulation No. 02-007

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION

NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF THE DEPARTMENT OF PESTICIDE REGULATION

Pesticide Safety Studies Involving Human Participants

December 6, 2002

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A Department of the California Environmental Protection Agency

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION
Pertaining to Pesticide Safety Studies Involving Human Participants
DPR Regulation No. 02-007

NOTICE OF PROPOSED REGULATORY ACTION

The Department of Pesticide Regulation (DPR) proposes to amend sections 6000 and 6710 of Title 3, California Code of Regulations. The proposed regulatory action pertains to the process by which DPR approves scientific protocols from an ethical and technical perspective for California-based pesticide exposure studies that involve human participants. DPR adopted emergency regulations that became effective on July 18, 2002. The proposed regulatory action would make permanent these emergency regulations. The text of proposed regulations differs slightly from the emergency regulations now in effect.

SUBMITTAL OF COMMENTS

Any interested person may present comments in writing about the proposed action to the agency contact person named below. Written comments must be received no later than 5:00 p.m. on January 20, 2003. Comments regarding this proposed action may also be transmitted via e-mail <dpr02007@cdpr.ca.gov> or by facsimile (FAX) transmission at (916) 324-1452.

A public hearing is not scheduled. However, a public hearing will be scheduled if any interested person submits a written request for a public hearing to DPR no later than 15 days prior to the close of the written comment period.¹

EFFECT ON SMALL BUSINESS

DPR has determined that the proposed regulatory action does affect small businesses.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Before a pesticide can be offered for sale for use in California, it has to be registered by DPR. Applicants for pesticide product registration must submit various studies to DPR regarding the product. In addition, DPR scientists conduct field studies each year to monitor worker exposure to pesticides. These studies help develop better methods to evaluate exposure and to prevent overexposure. Pesticide exposure studies are necessary in order to provide reliable and accurate exposure estimates for risk assessment. Using human participants enables researchers to obtain more relevant data regarding human health effects than could be obtained from animal studies. Because of the wide variety of climatic conditions and the diversity of crops grown in California, researchers can conduct a wide variety of human exposure studies within the state.

¹ If you have special accommodation or language needs, please include this in your request for a public hearing. TTY/TDD speech-to-speech users may dial 7-1-1 for the California Relay Service.

Scientific studies are usually conducted according to a generally accepted or standardized procedure known as a protocol. A good protocol can help ensure that valid, consistent results are obtained. Carefully designed protocols are especially important when people will be exposed to pesticides during the study.

Section 6710 states that no person shall conduct any pesticide exposure study in California, which involves human participants, unless the DPR Director has given written approval of the protocol. The study shall be conducted in accordance with the approved protocol. Concurrent review of protocols by the Office of Environmental Health Hazard Assessment (OEHHA) is also required. Protocols are reviewed from an ethical perspective, and technical guidance on the conduct of the study may be provided as well.

Section 6710 covers what is to be included in a protocol for this type of study. Items to be addressed include, among others, pesticide labeling directions and rates to be used, proposed starting and completion dates of the study, background and justification for the study, study design, methods to be used, selection process for human participants, criteria for exclusion or inclusion of these participants, written consent, medical supervision, and compensation.

Section 6710(c) requires DPR to submit these protocols to an appropriate committee of a public or private California research university, which has an agreement with DPR to review protocols with regard to use of human participants in research. After an ethical review of the protocol, the committee made a recommendation to DPR regarding approval of the protocol. The DPR Director then made the final decision and informed the registrant of the decision.

DPR contracted with the University of California at San Francisco (UCSF) to have its Committee on Human Research (CHR) review protocols for studies to be conducted by DPR's Worker Health and Safety Branch scientists. For a fee, CHR also reviewed protocols submitted to DPR by pesticide registrants, task forces, consultants, and others. DPR reviewed the protocols from a health and safety perspective and forwarded them to CHR for an ethical review.

On May 25, 2001, DPR noticed a proposed regulatory action in the *California Regulatory Notice Register* to amend section 6710(d) to reflect the increased cost of the protocol reviews. On September 7, 2001, DPR adopted the proposed action and delivered the rulemaking file to the Office of Administrative Law (OAL) for approval. Soon after this, UCSF informed DPR that it would no longer be reviewing the protocols. DPR subsequently withdrew the rulemaking file from OAL on September 17, 2001.

Since that time, DPR attempted without success to find another public or private California university to review the protocols. Since the text of section 6710 was based upon the guidelines and requirements of CHR, it was necessary for DPR to completely revise it to provide an alternative means of ensuring appropriate ethical review of the protocols.

The proposed regulations would require a study director to obtain an Institutional Review

Board (IRB) to conduct the ethical review of a protocol involving a California pesticide study using human participants. The study director would be required to submit all protocols directly to the IRB. DPR would accept an IRB's review provided it meets the requirements as specified in Title 40, Code of Federal Regulations, Protection of Environment, Part 26, Protection of Human Subjects, and provides adequate protection to the participants. In overseeing the entire protocol review process, DPR will also consider recommendations from the IRB and OEHHA prior to approving the protocol.

As part of the regulatory proposal, DPR has included new definitions in section 6000. These definitions are needed to clarify for section 6710 what is meant by "human participant," "Institutional Review Board (IRB)," and "study director." The definition of "pesticide exposure study" has been amended.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the State pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. DPR has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

DPR has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

DPR has determined that no costs or savings in federal funding to the State will result from the proposed action.

EFFECT ON HOUSING COSTS

DPR has made an initial determination that the proposed action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESSES

DPR has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

DPR has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. However, representative private persons or businesses may incur a cost in reasonable compliance with the proposed action.

Pesticide registrants, task forces, and consultants are typical of the businesses that submit protocols to DPR. DPR staff expect about 12 protocols per year to require participation and review by an IRB. Some of these protocols will be for new studies and the others will be for previously approved protocols that are up for renewal. CHR has charged these businesses \$300 per protocol review. As described previously in this notice, CHR is no longer providing this service and no other public or private California university has been found that is willing to review the protocols.

Based upon surveys of IRBs, it is expected that a fee of about \$1,300-\$1,500 per protocol will be charged for review. Thus, each protocol could now incur an additional cost of about \$1,200 beyond what was paid previously to CHR. However, prior to discontinuing their protocol review service, CHR had informed DPR that it would be raising its rate from the existing \$300 fee per protocol to \$1,400. In some cases, the cost to review a protocol will be less since it will be a renewal of a previously approved protocol. The cost of review of previously approved protocols that are up for renewal is expected to be about \$300-\$600. The sponsor of the research study will pay the fee to the members of the IRB that has been designated to review the protocol. The sponsor will also incur some of the other costs currently borne by DPR, including staff time involved with receiving the protocols and submitting them to CHR, in addition to the costs of reproduction, shipping, and interacting with CHR.

A majority of the protocol submitters are large businesses. Consulting firms are small businesses but they usually conduct the research which is subsequently paid for by pesticide registrants. Pesticide registrants are usually, but not always, large businesses. Considering that federal and state pesticide registration is often a lengthy, costly process, DPR feels that this cost impact is not significant to representative private persons or businesses. These several-hundred-dollar protocol review costs are all extremely small in comparison to the total cost of a research study.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS

DPR has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business with the State of California.

CONSIDERATION OF ALTERNATIVES

DPR must determine that no reasonable alternative considered by the agency, or that has otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons

or businesses than the proposed regulatory action.

AUTHORITY

This regulatory action is taken pursuant to the authority vested by Food and Agricultural Code sections 12976, and 12981.

REFERENCE

This regulatory action is to implement, interpret, or make specific Food and Agricultural Code sections 12980, 12981, 12987, and 12988.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

DPR has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which DPR relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After the close of the comment period, DPR may make the regulation permanent if it remains substantially the same as described in the Informative Digest. If DPR does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. DPR will accept written comments on any changes for 15 days after the modified text is made available.

AGENCY CONTACT

Written comments about the proposed regulatory action; requests for a copy of the Initial Statement of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

Fred Bundock, Regulatory Program Specialist
Office of Legislation and Regulations
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015
(916) 324-4194

Note: In the event the contact person is unavailable, inquiries should be directed to the following backup contact person at the same address as noted above:

Linda Irokawa-Otani, Regulations Coordinator
(916) 445-3991

Questions on the substance of the proposed regulatory action may be directed to:

Jim Goodbrod, D.V.M.
Associate Environmental Research Scientist
Worker Health and Safety Branch
Department of Pesticide Regulation
(916) 323-7617

This Notice of Proposed Action, the Initial Statement of Reasons, and the proposed text of the regulation are also available on DPR's Internet Home Page <<http://www.cdpr.ca.gov>>.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9(a) may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on DPR's Internet Home Page and accessed at <<http://www.cdpr.ca.gov>>.

DEPARTMENT OF PESTICIDE REGULATION

Director

Date